

United States Patent and Trademark Office

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address: COMMISSIONER FOR PATENTS P.O. Box 1450 Alexandria, Virginia 22313-1450 www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO
10/785,168	02/23/2004	Joseph R. Testa	0492611-0476 (MIT 9700)	8498
110	7590 08/25/2006		EXAMINER	
DANN, DORFMAN, HERRELL & SKILLMAN			EPPS FORD, JANET L	
1601 MARKET STREET SUITE 2400 PHILADELPHIA, PA 19103-2307		ART UNIT	PAPER NUMBER	
		1633		

DATE MAILED: 08/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)
0.00 - 4.41 - 0	10/785,168	TESTA ET AL.
Office Action Summary	Examiner	Art Unit
	Janet L. Epps-Ford	1633
The MAILING DATE of this communication app Period for Reply	pears on the cover sheet with the c	orrespondence address
A SHORTENED STATUTORY PERIOD FOR REPLY WHICHEVER IS LONGER, FROM THE MAILING D/ Extensions of time may be available under the provisions of 37 CFR 1.1: after SIX (6) MONTHS from the mailing date of this communication. If NO period for reply is specified above, the maximum statutory period v Failure to reply within the set or extended period for reply will, by statute Any reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b).	ATE OF THIS COMMUNICATION 36(a). In no event, however, may a reply be tim will apply and will expire SIX (6) MONTHS from . cause the application to become ABANDONE	I. lely filed the mailing date of this communication. D (35 U.S.C. § 133).
Status		
1) Responsive to communication(s) filed on 2a) This action is FINAL . 2b) This 3) Since this application is in condition for allowar closed in accordance with the practice under E	action is non-final.	
Disposition of Claims		
4) Claim(s) 1-68 is/are pending in the application. 4a) Of the above claim(s) is/are withdray 5) Claim(s) is/are allowed. 6) Claim(s) is/are rejected. 7) Claim(s) is/are objected to. 8) Claim(s) 1-68 are subject to restriction and/or example. Application Papers 9) The specification is objected to by the Examine	wn from consideration. election requirement.	
10) The drawing(s) filed on is/are: a) access applicant may not request that any objection to the Replacement drawing sheet(s) including the correct all The oath or declaration is objected to by the Ex	drawing(s) be held in abeyance. See ion is required if the drawing(s) is obj	e 37 CFR 1.85(a). ected to. See 37 CFR 1.121(d).
Priority under 35 U.S.C. § 119		
12) Acknowledgment is made of a claim for foreign a) All b) Some * c) None of: 1. Certified copies of the priority documents 2. Certified copies of the priority documents 3. Copies of the certified copies of the prior application from the International Bureau * See the attached detailed Office action for a list	s have been received. s have been received in Application rity documents have been received u (PCT Rule 17.2(a)).	on No ed in this National Stage
Attachment(s) 1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date	4) Interview Summary Paper No(s)/Mail Da 5) Notice of Informal P 6) Other:	

DETAILED ACTION

Election/Restrictions

- 1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
 - I. Antisense targeting human APPL nucleic acid and methods of use:
 - i. Claims 4, 24, drawn to antisense (SEQ ID NO: 1) and a pharmaceutical composition comprising said antisense, classified in class 536, subclass 24.5.
 - ii. Claims 5, 25, drawn to antisense (SEQ ID NO: 2) and a pharmaceutical composition comprising said antisense, classified in class 536, subclass 24.5.
 - iii. Claims 6, 26, drawn to antisense (SEQ ID NO: 4) and a pharmaceutical composition comprising said antisense, classified in class 536, subclass 24.5.

It is noted that claims 1-3, 7-23, 27-33 are considered to link the above inventions.

Invention groups i-iii are considered patentably distinct inventions since they are drawn to antisense compositions (and methods of use) comprising distinct nucleotide sequence structures. The search of each of these antisense compounds are non-coextensive, therefore a separate search and consideration of the prior art is required for each of the above inventions.

Application/Control Number: 10/785,168 Page 3

Art Unit: 1633

II. double-stranded RNA targeting human APPL nucleic acid and methods of

use:

i. siRNA and methods of use: claims 35, 37 (SEQ ID NO: 6), 39, 41-

42, 45-46, 49-50, 53-60.

ii. shRNA and methods of use: claims 36, 38 (SEQ ID NO: 8), 40, 43-

44, 47-48, 51-52, 61-68.

Claim 34 is a linking claim for the above inventions.

Invention groups i-ii are considered patentably distinct inventions since

they are drawn to patentably distinct double stranded RNA compounds

(and methods of use) comprising distinct nucleotide sequence structures.

The search of each of these dsRNA compounds are non-coextensive.

therefore a separate search and consideration of the prior art is required

for each of the above inventions.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I and II are unrelated. Inventions are unrelated if it can be shown that

they are not disclosed as capable of use together and they have different designs,

modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the

different inventions are patentably distinct since they are drawn to distinct chemical

compounds, specifically antisense (SEQ ID NOs: 1, 2, and 4), and double stranded

RNA (SEQ ID NO: 6 and 8) compounds. Each of these compounds comprise a distinct

chemical structure, and require a separate search and consideration of the prior art.

Antisense compounds may include both DNA and RNA oligonucleotides, however

Art Unit: 1633

dsRNA are comprised of RNA. Each of these sequences comprise a distinct nucleotide sequence as well. The antisense compounds of the invention include those having a sequence according to SEQ ID NO: 1, 2, and 4, and the dsRNA compounds of the invention include those that have a sequence according to SEQ ID NO: 6 and 8. Furthermore, antisense compounds are functionally distinct from dsRNA compounds since they inhibit the expression of their target nucleic acids by distinct molecular pathways.

- 3. Because these inventions are independent or distinct for the reasons given above and the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.
- 4. This application contains claims directed to the following patentably distinct species: a) human cells: selected from skeletal muscle, heart, ovary, and pancreas; b) a plurality of anti-cancer agents selected from cisplatin, carboplatin, herceptin, taxol, taxane derivatives, cyclophosphamide, methotrexate, vincristin, and etopside. The species are independent or distinct because a) the various human cells recited in the instant claims are patentably distinct as they are directed to distinct classes of cells which are known in the art to express a distinct set of genes and express a distinct set of molecular markers. The search of each of these individual classes of cells requires a separate search and consideration of the prior art. Furthermore, the various anti-cancer compounds listed in the claims are structurally distinct chemical compounds that require a separate search and consideration of the prior art.

Art Unit: 1633

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, 1-68 are generic to the disclosed species.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

- 5. Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.
- 6. The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Application/Control Number: 10/785,168

Art Unit: 1633

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Page 6

Art Unit: 1633

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Epps-Ford whose telephone number is 571-272-0757. The examiner can normally be reached on M-F, 10:00 AM through 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave T. Nguyen can be reached on 571-272-0731. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 574-272-1000.

Primary Examine

Art Unit 1633